

## APPENDIX A FDA Approved Oncology Drugs

Atty. Docket No.: 2003946-0110 Client Ref.: ANDI/US

Customer No.: 24280

Drug	Drug Trade Name	Approved Use	Manufacturer/Distributor	Approval Date
alitretinoin	<u>Panretin</u>	Topical treatment of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma.	Ligand Pharmaceuticals	Feb 02 1999
<u>allopurinol</u>	<u>Zyloprim</u>	Patients with leukemia, lymphoma and solid tumor malignancies who are receiving cancer therapy which causes elevations of serum and urinary uric acid levels and who cannot tolerate oral therapy.	Glaxo Smith Kline	May 17 1996
<u>altretamine</u>	<u>Hexalen</u>	Single agent palliative treatment of patients with persistent or recurrent ovarian cancer following first-line therapy with a cisplatin and/or alkylating agent based combination.	<u>US Bioscience</u>	Dec 26 1990
<u>amifostine</u>	<u>Ethyol</u>	To reduce the cumulative renal toxicity associated with repeated administration of cisplatin in patients with advanced ovarian cancer	US Bioscience	Dec 08 1995
<u>amifostine</u>	Ethyol	Reduction of platinum toxicity in non-small cell lung cancer	US Bioscience	Mar 15 1996
amifostine	<b>Ethyol</b>	To reduce post-radiation xerostomia for head and neck cancer where the radiation port includes a substantial portion of the parotid glands.	US Bioscience	Jun 24 1999
anastrozole	<u>Arimidex</u>	for the adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer	<u>AstraZeneca</u>	Sep 05 2002
<u>anastrozole</u>	Arimidex	Treatment of advanced breast cancer in postmenopausal women with disease progression following tamoxifen therapy.	AstraZeneca Pharmaceuticals	Dec 27 1995
anastrozole	<u>Arimidex</u>	For first-line treatment of postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer.	AstraZeneca Pharmaceuticals	Sep 01 2000
arsenic trioxide	<u>Trisenox</u>	Second line treatment of relapsed or refractory APL following ATRA plus an anthracycline.	Cell Therapeutic	Sep 25 2000
<u>bexarotene</u>	Targretin	For the treatment by oral capsule of cutaneous manifestations of cutaneous T-cell lymphoma in patients who are refractory to at least one prior systemic therapy.	Ligand Pharmaceuticals	Dec 29 1999
<u>bexarotene</u>	Targretin	For the topical treatment of cutaneous manifestations of cutaneous T-cell lymphoma in patients who are refractory to at least one prior systemic therapy.	Ligand Pharmaceuticals	Jun 28 2000
bleomycin	<u>Blenoxane</u>	Sclerosing agent for the treatment of malignant pleural effusion (MPE) and prevention of recurrent pleural effusions.	Bristol-Myers Squibb	Feb 20 1996
<u>busulfan</u> intravenous	Dusunex	Use in combination with cyclophoshamide as conditioning regimen prior to allogeneic hematopoietic progenitor cell transplantation for chronic myelogenous leukemia.	Orphan Medical, Inc	Feb 04 1999
		Chronic Myelogenous Leukemia- palliative		Jun 26



<u>busulfan oral</u>	<u>Myleran</u>	therapy	Glaxo Smith Kline	1954
capecitabine	<u>Xeloda</u>	Initial therapy of patients with metastatic colorectal carcinoma when treatment with fluoropyrimidine therapy alone is preferred. Combination chemotherapy has shown a survival benefit compared to 5-FU/LV alone. A survival benefit over 5_FU/LV has not been demonstrated with Xeloda monotherapy.	<u>Roche</u>	Apr 30 2001
capecitabine	<u>Xeloda</u>	Treatment in combination with docetaxel of patients with metastatic breast cancer after failure of prior anthracycline containing chemotherapy	Roche .	Sep 07 2001
capecitabine	<u>Xeloda</u>	Treatment of metastatic breast cancer resistant to both paclitaxel and an anthracycline containing chemotherapy regimen or resistant to paclitaxel and for whom further anthracycline therapy may be contraindicated, e.g., patients who have received cumulative doses of 400 mg/m2 of doxorubicin or doxorubicin equivalents	Roche	Apr 30 1998
carboplatin -	<u>Paraplatin</u>	Palliative treatment of patients with ovarian carcinoma recurrent after prior chemotherapy, including patients who have been previously treated with cisplatin.	Bristol-Myers Squibb	Mar 03 1989
carboplatin	<u>Paraplatin</u>	Initial chemotherapy of advanced ovarian carcinoma in combination with other approved chemotherapeutic agents.	Bristol-Myers Squibb	Jul 05 1991
carmustine with Polifeprosan 20 Implant	Gliadel Wafer	For use in addition to surgery to prolong survival in patients with recurrent glioblastoma multiforme who qualify for surgery.	Guilford Pharmaceuticals Inc.	Sep 23 1996
celecoxib	<u>Celebrex</u>	Reduction of polyp number in patients with the rare genetic disorder of familial adenomatous polyposis.	Searle Searle	Dec 23 1999
chlorambucil	<u>Leukeran</u>	Chronic Lymphocytic Leukemia- palliative therapy	Glaxo Smith Kline	
eisplatin	<u>Platinol</u>	as a single agent for patients with transitional cell bladder cancer which is no longer amenable to local treatments such as surgery and/or radiotherapy.	Bristol-Myers Squibb	Apr 22 1993
<u>sisplatin</u>	<u>Platinol</u>	Metastatic testicular-in established combination therapy with other approved chemotherapeutic agents in patients with metastatic testicular tumors whoc have already received appropriate surgical and/or radiotherapeutic procedures. An established combination therapy consists of Platinol, Blenoxane and Velbam.	Bristol-Myers Squibb	Dec 19 1978
	·	Metastatic ovarian tumors - in established combination therapy with other approved chemotherapeutic agents: Ovarian-in established combination therapy with other		

cytarabine liposomal daunorubicin liposomal daunorubicin daunorubicin liposomal daunorubicin liposomal daunorubicin liposomal daunorubicin liposomal daunorubicin of adults/remission induction in acute lymphocytic leukemia of children and adults.  Leukemia/myelogenous/monocytic/erythroid of adults/remission induction in acute lymphocytic leukemia of children and adults.  Cerubidine liposomal daunorubicin of adults/remission induction in acute lymphocytic leukemia of children and adults.  In combination with approved anticancer drugs for induction of remission in adult ALL.  Cerubidine reducing the incidence and severity of cardiomyopathy associated with doxorubicin administration in women with metastatic breast cancer who have received a cumulative doxrubicin dose of 300 mg/m2 and who will continue to receive doxorubicin therapy to maintain turnor control. It is not recommended for use with the initiation of doxorubicin therapy.  dextazzoxane Zinecard Prevention of cardiomyopathy associated with doxorubicin doministration or metastatic breast cancer who have progressed during anthracycline-based therapy or have relapsed during anthracycline-based adjuvant therapy.  docetaxel Taxotere For locally advanced or metastatic breast cancer which has progressed during anthracycline-based treatment or relapsed during anthracycline-based adjuvant therapy.  For the treatment of locally advanced or metastatic breast cancer which has progressed during anthracycline-based treatment or relapsed during anthracycline-based adjuvant therapy.  Addiamycin Addiamycin Antibiotic antitumor agent Pharmacia & Upjohn Dec 23	<u>cisplatin</u>	<u>Platinol</u>	approved chemotherapeutic agents in patients with metastatic ovarian tumors who have already received appropriate surgical and/or radiotherapeutic procedures. An established combination consists of Platinol and Adriamycin. Platinol, as a single agent, is indicated as secondary therapy in patients with metastatic ovarian tumors refractory to standard chemotherapy who have not previously received Platinol therapy.	Bristol-Myers Squibb	Dec 19 1978
cytarabine cytarabine liposomal  daunorubicin liposomal  daunorubicin daunorubicin daunorupicin	<u>epinephrine</u>	(R), FocaCis	not approved	Matrix Pharmaceutical	
DanuoXome   DanuoXome   First line cytotoxic therapy for advanced, HIV   related Kaposi's sarcoma.   Leukemia/myelogenous/monocytic/erythroid   daunorubicin, daunorubicin, daunorubicin, daunorubicin, daunomycin   Daunorubicin of adults/remission induction in acute lymphocytic leukemia of children and adults.   Bedford Labs   Jan 30 1998	<u>cladribine</u>		Treatment of active hairy cell leukemia.	Pharmaceutical Research	Feb 26 1993
Ijopsomal   January		<u>DepoCyt</u>		Skye Pharmaceuticals	Apr 01 1999
Daunorubicin   Daun		<u>DanuoXome</u>		Nexstar, Inc.	Apr 08 1996
dexrazoxane    Authinitical Pharmacia   Cerubidine   drugs for induction of remission in adult ALL   Myeth Ayerst Res   1987		<u>Daunorubicin</u>	of adults/remission induction in acute	Bedford Labs	Jan 30 1998
Cardiomyopathy associated with doxorubicin administration in women with metastatic breast cancer who have received a cumulative doxorubicin dose of 300 mg/m2 and who will continue to receive doxorubicin therapy to maintain tumor control. It is not recommended for use with the initiation of doxorubicin therapy.    December   Prevention of cardiomyopathy associated with doxorubicin administration   Pharmacia & Upjohn Company   1995		<u>Cerubidine</u>		Wyeth Ayerst Res	Mar 11 1987
docetaxel  Taxotere  Taxotere  Taxotere  Taxotere  Taxotere  Taxotere  Taxotere  Taxotere  To locally advanced or metastatic non-small cell lung cancer after failure of prior platinum-based chemotherapy.  To the treatment of locally advanced or metastatic breast cancer which has progressed during anthracycline-based adjuvant therapy.  To the treatment of locally advanced or metastatic non-small cell lung cancer after failure of prior platinum-based chemotherapy.  To the treatment of locally advanced or metastatic breast cancer which has progressed during anthracycline-based treatment or relapsed during anthracycline-based adjuvant therapy.  Adriamycin  Antibiotic antitumor agent  Antibiotic antitumor agent  Company  Aventis Pharmaceutical  Aventis Pharmaceutical  Pharmacia & Upjohn  Dec 23	<u>dexrazoxane</u>	<u>Zinecard</u>	cardiomyopathy associated with doxorubicin administration in women with metastatic breast cancer who have received a cumulative doxorubicin dose of 300 mg/m2 and who will continue to receive doxorubicin therapy to maintain tumor control. It is not recommended for use with the initiation of doxorubicin		
metastatic breast cancer who have progressed during anthracycline-based therapy or have relapsed during anthracycline-based adjuvant therapy.  For locally advanced or metastatic non-small cell lung cancer after failure of prior platinum-based chemotherapy.  For the treatment of locally advanced or metastatic breast cancer which has progressed during anthracycline-based treatment or relapsed during anthracycline-based adjuvant therapy.  Adriamycin  Antibiotic antitumor agent  May 14 1996  Aventis Pharmaceutical  Aventis Pharmaceutical  Aventis Pharmaceutical  Aventis Pharmaceutical  Pharmacia & Upjohn  Dec 23	<u>dexrazoxane</u>	Zinecard	Prevention of cardiomyopathy associated with doxorubicin administration		May 26 1995
docetaxel  Taxotere    Cell lung cancer after failure of prior platinum-based chemotherapy.   Aventis Pharmaceutical   Dec 23	docetaxel	<u>Taxotere</u>	metastatic breast cancer who have progressed during anthracycline-based therapy or have relapsed during anthracycline-based adjuvant	•	May 14 1996
metastatic breast cancer which has progressed during anthracycline-based treatment or relapsed during anthracycline-based adjuvant therapy.    Adriamycin	docetaxel	<u>Taxotere</u>	cell lung cancer after failure of prior platinum-	Aventis Pharmaceutical	Dec 23 1999
dovorablem 1 Antibione animmor agent	<u>docetaxel</u>		metastatic breast cancer which has progressed during anthracycline-based treatment or relapsed during anthracycline-based adjuvant	Aventis Pharmaceutical	
PFS Injection Antibiotic, antitumor agent. Company 1987	doxorubicin	Adriamycin PFS Injection	Antibiotic, antitumor agent.		Dec 23 1987

doxorubicin liposomal	<u>Doxil</u>	Treatment of AIDS-related Kaposi's sarcoma in patients with disease that has progressed on prior combination chemotherapy or in patients who are intolerant to such therapy.		Nov 17 1995
doxorubicin liposomal	<u>Doxil</u>	Treatment of metastatic carcinoma of the ovary in patient with disease that is refractory to both paclitaxel and platinum based regimens	Sequus Pharmaceuticals, Inc.	Jun 28 1999
Ellion's B Solution	Elliott's B Solution	Diluent for the intrathecal administration of methotrexate sodium and cytarabine for the prevention or treatment of meningeal leukemia or lymphocytic lymphoma.	Orphan Medical, Inc	Sep 27 1996
epirubicin	Ellence	A component of adjuvant therapy in patients with evidence of axillary node tumor involvement following resection of primary breast cancer.	Pharmacia & Upjohn Company	Sep 15 1999
<u>estramustine</u>	Emcyt	palliation of prostate cancer	Pharmacia & Upjohn Company	Dec 24 1981
etoposide phosphate	<u>Etopophos</u>	Management of refractory testicular tumors, in combination with other approved chemotherapeutic agents.	Bristol-Myers Squibb	May 17 1996
etoposide phosphate	Etopophos	Management of refractory testicular tumors and small cell lung cancer.	Bristol-Myers Squibb	Feb 27 1998
etoposide phosphate	<u>Etopophos</u>	Management of small cell lung cancer, first- line, in combination with other approved chemotherapeutic agents.	Bristol-Myers Squibb	May 17 1996
etoposide. VP-16	<u>VePesid</u>	In combination with other approved chemotherapeutic agents as first line treatment in patients with small cell lung cancer.	Bristol-Myers Squibb	Dec 30 1986
etoposide, VP-16	Vepesid	Refractory testicular tumors-in combination therapy with other approved chemotherapeutic agents in patients with refractory testicular tumors who have already received appropriate surgical, chemotherapeutic and radiotherapeutic therapy.	Bristol-Myers Squibb	Nov 10 1983
etoposide, VP-16	Vepesid	In combination with other approved chemotherapeutic agents as first line treatment in patients with small cell lung cancer.	Bristol-Myers Squibb	Dec 30 1986
<u>exemestane</u>	Aromasin	Treatment of advance breast cancer in postmenopausal women whose disease has progressed following tamoxifen therapy.	Pharmacia & Upjohn Company	Oct 21 1999
<u>fludarabine</u>	Fludara	Palliative treatment of patients with B-cell lymphocytic leukemia (CLL) who have not responded or have progressed during treatment with at least one standard alkylating agent containing regimen.	Berlex Laboratories Inc.	Apr 18 1991
fluorouracil, 5-FU	Adrucil	prolong survival in combination with leucovorin	ICN Puerto Rico	Apr 25 1962
fulvestrant	<u>Faslodex</u>	the treatment of hormone receptor-positive metastatic breast cancer in postmenopausal women with disease progression following	<u>IPR</u>	Apr 25 2002

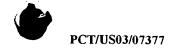




	ļ	antiestrogen therapy		
gemcitabine	<u>Gemzar</u>	For use in combination with cisplatin for the first-line treatment of patients with inoperable locally advanced (Stage IIIA or IIIB) or metastatic (Stage IV) non-small cell lung cancer.	Eli Lilly And Company	Aug 25 1998
gemcitabine	Gemzar	Treatment of patients with locally advanced (nonresectable stage II or III) or metastatic (stage IV) adenocarcinoma of the pancreas. Indicated for first-line treatment and for patients previously treated with a 5-fluorouracil-containing regimen.	Eli Lilly And Company	May 15 1996
gemtuzumab- ozogamicin	Mylotarg	Treatment of CD33 positive acute myeloid leukemia in patients in first relapse who are 60 years of age or older and who are not considered candidates for cytotoxic chemotherapy.	Wyeth Ayerst Res	May 17 2000
goserelin acetate	Zoladex Implant	Palliative treatment of advanced breast cancer in pre- and perimenopausal women.	AstraZeneca Pharmaceuticals	Dec 18 1995
<u>hydroxyurea</u>	<u>Hydrea</u> <u>Capsules</u>	Decrease need for transfusions in sickle cell anemia	Bristol-Myers Squibb	Feb 25 1998
<u>idarubicin</u>	<u>Idamycin</u>	For use in combination with other approved antileukemic drugs for the treatment of acute myeloid leukemia (AML) in adults.	Adria Laboratories	Sep 27 1990
<u>idarubicin</u>	Idamycin	In combination with other approved antileukemic drugs for the treatment of acute non-lymphocytic leukemia in adults.	Pharmacia & Upjohn Company	Feb 17 1997
<u>ifosfamide</u>	<u>IFEX</u>	Third line chemotherapy of germ cell testicular cancer when used in combination with certain other approved antineoplastic agents.	Bristol-Myers Squibb	Dec 30 1988
<u>imatinib</u> <u>mesylate</u>	<u>Gleevec</u>	metastatic or unresectable malignant gastrointestinal stromal tumors	<u>Novartis</u>	Feb 01 2002
<u>imatinib</u> mesylate	<u>Gleevec</u>	Initial therapy of chronic myelogenous leukemia	<u>Novartis</u>	May 10 2001
irinotecan	<u>Camptosar</u>	Treatment of patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed following 5-FU-based therapy.	Pharmacia & Upjohn Company	Jun 14 1996
irinotecan	Camptosar	For first line treatment n combination with 5-FU/leucovorin of metastatic carcinoma of the colon or rectum.	Pharmacia & Upjohn Company	Apr 20 2000
irinotecan	Camptosar	Follow up of treatment of metastatic carcinoma of the colon or rectum whose disease has recurred or progressed following 5-FU-based therapy.	Pharmacia & Upjohn Company	Oct 22 1998
<u>letrozole</u>	<u>Femara</u>	Treatment of advanced breast cancer in postmenopausal women.	Novartis	Jul 25 1997
letrozole	<u>Femara</u>	First-line treatment of postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or	<u>Novartis</u>	Jan 10 2001

<del></del>		metastatic breast cancer.  Leucovorin calcium is indicated fro use in		
leucovorin	Wellcovorin, Leucovorin	combination with 5-fluorouracil to prolong survival in the palliative treatment of patients with advanced colorectal cancer.	Immunex Corporation	Jun 20 1952
leucovorin	Leucovorin	In combination with fluorouracil to prolong survival in the palliative treatment of patients with advanced colorectal cancer.	Lederle Laboratories	Dec 12 1991
evamisole	Ergamisol	Adjuvant treatment in combination with 5- fluorouracil after surgical resection in patients with Dukes' Stage C colon cancer.	Janssen Research Foundation	Jun 18 1990
liposomal daunorubicin	<u>DaunoXome</u>	"DaunoXome is indicated as a first line cytotoxic therapy for advanced HIV-associated Kaposi's Sarcoma. DaunoXome is not recommended in patients with less than advnanced HIV-related Kaposi's Sarcoma."	<u>Vestar, Inc</u>	Jan 28 1994
melphalan, L- PAM	Alkeran	Systemic administration for palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate.	Glaxo Smith Kline	Nov 18 1992
mesna	Mesnex	Prevention of ifosfamide-induced hemorrhagic cystitis	Asta Medica	Dec 30 1988
methotrexate	Methotrexate	osteosarcoma	Lederle Laboratories	Apr 07 1988
methoxsalen	<u>Uvadex</u>	For the use of UVADEX with the UVAR Photopheresis System in the palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (CTCL) that is unresponsive to other forms of treatment.	<u>Therakos</u>	Feb 25 1999
mitomycin C	<u>Mitozytrex</u>	therapy of disseminated adenocarcinoma of the stomach or pancreas in proven combinations with other approved chemotherapeutic agents and as palliative treatment when other modalities have failed.	<u>Supergen</u>	Nov 14 2002
mitoxantrone	<u>Novantrone</u>	For use in combination with corticosteroids as initial chemotherapy for the treatment of patients with pain related to advanced hormone-refractory prostate cancer.	Immunex Corporation	Nov 13 1996
mitoxantrone	<u>Novantrone</u>	For use with other approved drugs in the initial therapy for acute nonlymphocytic leukemia (ANLL) in adults.	Lederle Laboratories	Dec 23 1987
paclitaxel	<u>Paxene</u>	treatment of advanced AIDS-related Kaposi's sarcoma after failure of first line or subsequent systemic chemotherapy	Baker Norton Pharmaceuticals, Inc	Dec 24 1997
paclitaxel	<u>Taxol</u>	For first-line therapy for the treatment of advanced carcinoma of the ovary in combination with cisplatin.	Bristol-Myers Squibb	Apr 09 1998
<u>paclitaxel</u>	<u>Taxol</u>	Treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically	Bristol-Myers Squibb	Apr 13 1994

	·	contraindicated.		1
paclitaxel	<u>Taxol</u>	for use in combination with cisplatin, for the first-line treatment of non-small cell lung cancer in patients who are not candidates for potentially curative surgery and/or radiation therapy.	Bristol-Myers Squibb	Jun 30 1998
<u>paclitaxel</u>	<u>Taxol</u>	For the adjuvant treatment of node-positive breast cancer administered sequentially to standard doxorubicin-containing combination therapy.	Bristol-Myers Squibb	Oct 25 1999
<u>paclitaxel</u>	<u>Taxol</u>	First line ovarian cancer with 3 hour infusion.	Bristol-Myers Squibb	Jun 20 2000
<u>paclitaxel</u>	<u>Taxol</u>	New dosing regimen for patients who have failed initial or subsequent chemotherapy for metastatic carcinoma of the ovary	Bristol-Myers Squibb	Jun 22 1994
<u>paclitaxel</u>	<u>Taxol</u>	Treatment of patients with metastatic carcinoma of the ovary after failure of first-line or subsequent chemotherapy.	Bristol-Myers Squibb	Dec 29 1992
paclitaxel	<u>Taxol</u>	second line therapy for AIDS related Kaposi's sarcoma.	Bristol-Myers Squibb	Aug 04 1997
pamidronate	Aredia	Treatment of osteolytic bone metastases of breast cancer in conjunction with standard antineoplastic therapy.	<u>Novartis</u>	Sep 22 1998
Pegademase	Adagen (Pegademase Bovine)	Enzyme replacement therapy for patients with severe combined immunodeficiency as a result of adenosine deaminase deficiency.	<u>Enzon</u>	Mar 21 1990
pentostatin	<u>Nipent</u>	Single agent treatment for adult patients with alpha interferon refractory hairy cell leukemia.	Parke-Davis Pharmaceutical Co.	Oct 11 1991
<u>pentostatin</u>		Single-agent treatment for untreated hairy cell leukemia patients with active disease as defined by clinically significant anemia, neutropenia, thrombocytopenia, or disease-related symptoms. (Supplement for front -line therapy.)	Parke-Davis Pharmaceutical Co.	Sep 29 1993
oorfimer sodium	<u>Photofrin</u>	For use in photodynamic therapy (PDT) for palliation of patients with completely obstructing esophageal cancer, or patients with partially obstructing esophageal cancer who cannot be satisfactorily treated with NDYAG laser therapy.	QLT Phototherapeutics Inc.	Dec 27 1995
oorfimer oodium	<u>Photofrin</u>	For use in photodynamic therapy (PDT) for reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobroncial nonsmall cell lung cancer (NSCLC).	QLT Phototherapeutics Inc.	Dec 22 1998
oorfimer odium	<u>Photofrin</u>	For use in photodynamic therapy for treatment of microinvasive endobronchial nonsmall cell lung cancer in patients for whom surgery and radiotherapy are not indicated.	QLT Phototherapeutics Inc.	Jan 09 1998
treptozocin	Zanosar	Antineoplastic agent.	Pharmacia & Upjohn	May 07



	· 		Company	1982
talc_	Sclerosol	For the prevention of the recurrence of malignant pleural effusion in symptomatic patients.	<u>Bryan</u>	Dec 24 1997
amoxifen	<u>Nolvadex</u>	For use in women with axillary node-negative breast cancer adjuvant therapy.	AstraZeneca Pharmaceuticals	Jun 21 1990
tamoxifen	<u>Nolvadex</u>	As a single agent to delay breast cancer recurrence following total mastectomy and axillary dissection in postmenopausal women with breast cancer (T1-3, N1, M0)	AstraZeneca Pharmaceuticals	Dec 03 1986
amoxifen	<u>Nolvadex</u>	to reduce the incidence of breast cancer in women at high risk for breast cancer	AstraZeneca Pharmaceuticals	Oct 29 1998
amoxifen	<u>Nolvadex</u>	Metastatic breast cancer in men.	AstraZeneca Pharmaceuticals	Apr 01 1993
amoxifen	<u>Nolvadex</u>	to reduce the incidence of breast cancer in women at high risk for breast cancer	AstraZeneca Pharmaceuticals	Oct 29 1998
amoxifen	<u>Nolvadex</u>	In women with DCIS, following breast surgery and radiation, Nolvadex is indicated to reduce the risk of invasive breast cancer.	AstraZeneca Pharmaceuticals	Jun 29 2000
tamoxifen	<u>Nolvadex</u>	Equal bioavailability of a 20 mg Nolvadex tablet taken once a day to a 10 mg Nolvadex tablet taken twice a day.	AstraZeneca Pharmaceuticals	Mar 21 1994
tamoxifen	Nolvadex	For use in premenopausal women with metastatic breast cancer as an alternative to oophorectomy or ovarian irradiation	AstraZeneca Pharmaceuticals	Mar 16 1989
temozolamide	<u>Temodar</u>	Treatment of adult patients with refractory anaplastic astrocytoma, i.e., patients at first relapse with disease progression on a nitrosourea and procarbazine containing regimen	<u>Schering</u>	Aug 11 1999
teniposide, VM-26	<u>Vumon</u>	In combination with other approved anticancer agents for induction therapy in patients with refractory childhood acute lymphoblastic leukemia (all).	Bristol-Myers Squibb	Jul 14 1992
topotecan	<u>Hycamtin</u>	Treatment of patients with metastatic carcinoma of the ovary after failure of initial or subsequent chemotherapy.	Glaxo Smith Kline	May 28 1996
topotecan . :	Hycamtin	Treatment of small cell lung cancer sensitive disease after failure of first-line chemotherapy. In clinical studies submitted to support approval, sensitive disease was defined as disease responding to chemotherapy but subsequently progressing at least 60 days (in the phase 3 study) or at least 90 days (in the phase 2 studies) after chemotherapy	Glaxo Smith Kline	Nov 30 1998
toremifene	Fareston	Treatment of advanced breast cancer in postmenopausal women.	Orion Corp.	May 29 1997
tretinoin,	Vesanoid	Induction of remission in patients with acute promyelocytic leukemia (APL) who are refractory to or unable to tolerate	<u>Roche</u>	Nov 22





<u>ATRA</u>		anthracycline based cytotoxic chemotherapeutic regimens.	1	1995
valrubicin	<u>Valstar</u>	For intravesical therapy of BCG-refractory carcinoma in situ (CIS) of the urinary bladder in patients for whom immediate cystectomy would be associated with unacceptable morbidity or mortality.	Anthra> Medeva	Sep 25 1998
<u>vinorelbine</u>	Navelbine	Single agent or in combination with cisplatin for the first-line treatment of ambulatory patients with unresectable, advanced non-small cell lung cancer (NSCLC).	Glaxo Smith Kline	Dec 23 1994
<u>vinorelbine</u>	<u>Navelbine</u>	Navelbine is indicated as a single agent or in combination with cisplatin for the first-line treatment of ambulatory patients with unreseactable, advanced non-small cell lung cancer (NSCLC). In patients with Stage IV NSCLC, Navelbine is indicated as a single agent or in combination with cisplatin. In Stage III NSCLC, Navelbine is indicated in combination with cisplatin.	<u>GlaxoSmithKline</u>	Nov 05 2002
zoledronate	Zometa	the treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. Prostate cancer should have progressed after treatment with at least one hormonal therapy	<u>Novartis</u>	Feb 22 2002